

**REMARKS/ARGUMENTS**

**Information Disclosure Statement.**

Pages 2 to 4 of Cuthbertson (WO 02/26776) are enclosed.

**Claim Rejections: 35 USC §103(a)**

Claims 13, 14, 16-18 and 20-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Cuthbertson (WO02/26776). Claims 13-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Marten et al. Claims 13-15, 17, 18 and 20-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Weissleder et al. Applicants respond as follows:

Applicants submit revised claims 13-24, which is the subject matter of previous claim 14 that has been incorporated into revised claim 13. Previous claim 14 has consequently been cancelled. In addition, the “abnormally expressed biological target associated with CRC” in amended claim 13 has been limited to c-met, MMP-14, COX-2, beta-catenin and cathepsin B. Basis for the latter change is to be found in the specification at page 7 lines 11-12. Hence, the amendment does not add new matter. As a result of this change, previous claim 19 has also been cancelled.

**Cuthbertson (WO 02/26776)**

Applicants note that Cuthbertson (page 3 lines 1 to 4) refers to colorectal cancer (CRC) as being a condition which is associated with angiogenesis. The teaching of Cuthbertson relates, however, to targeting of integrin avb3. Cuthbertson does not suggest, disclose, or teach any other biological target. Furthermore, that particular biological target is outside the scope of the biological targets of revised Claim 13. Applicants therefore contend that modification of Cuthbertson in the manner suggested by the Examiner would give rise to subject matter outside the scope of amended claim 13. The 35 U.S.C. § 103(a) obviousness rejection to claim 13 and dependent claims 15 to 21 based on Cuthbertson should therefore be withdrawn.

Appl. No. 10/573,606  
Amdt. Dated September 13, 2007  
Reply to Office action of June 14, 2007

Claim 22 refers to claim 13, and hence by definition contains all the essential features of that claim. Claim 22 is therefore also believed inventive over Cuthbertson for analogous reasons.

With respect to Claim 23, the “diagnostic agent” product of the process is believed inventive for the reasons given above. Applicants therefore contend that the rejections to claim 23 based on Cuthbertson should also be withdrawn.

For claim 24, no description of the rejection(s) based on Cuthbertson was provided in the Office Action. Applicants point out, however, that claim 24 refers to the contrast agent of claim 13. Since revised claim 13 is believed inventive over Cuthbertson for the reasons given above, applicants contend that any rejections/objections to claim 24 should also be withdrawn.

Marten *et al.* [Gastroenterol., 122, 406-414 (2002)]

The Examiner suggests that it would have been obvious for the person skilled in the art to utilize the cathepsin B sensing NIR fluorochrome probes of Marten for imaging the colon. Applicants point out that the cathepsin B sensing probe of Marten is described on page 408 of Marten in the text subtitled “NIR Fluorochrome Probes”. The statement is made that:

“The assembly consisted of a synthetic graft copolymer containing partially pegylated (5 kDa) poly-L-lysine (35 kDa)....”

Marten states (same location) that the probe is described in more detail elsewhere (Reference 20). Reference 20 corresponds to Weissleder – see 2.4 (below). The experimental section of Weissleder (p. 377) states that the graft copolymer had an average molecular mass of 480 kDa. The probe of Marten thus far exceeds the molecular weight limit of 10,000 Daltons (10 kDa) of present claim 13.

Appl. No. 10/573,606  
Amdt. Dated September 13, 2007  
Reply to Office action of June 14, 2007

Use of the probes described by Marten in the manner suggested by the Examiner therefore falls outside the scope of revised Claim 13. Similar logic applies to claims 15-18 and 20-24 since these claims depend on, or refer to claim 13. Applicants contend that the 35 U.S.C. § 103(a) obviousness rejections based on Marten should therefore be withdrawn.

Weissleder [Nature Biotech., 17, 375-8 (1999)].

The NIRF probes of Weissleder are the same as those of Marten. The 35 U.S.C. § 103(a) obviousness inventive step rejection based on Weissleder should therefore be withdrawn for similar reasons to those given above in Marten et al. [Gastroenterol., 122, 406-414 (2002)].

**Provisional Obviousness-Type Double Patenting.**

Please find enclosed a terminal disclaimer vs the following applications:

|                                      |                         |
|--------------------------------------|-------------------------|
| Copending Application No.: 10/573604 | (our case ref. PN0369); |
| Copending Application No.: 10/582679 | (our case ref. PN0397); |
| Copending Application No.: 10/582680 | (our case ref. PN0399); |
| Copending Application No.: 10/582842 | (our case ref. PN0396); |
| Copending Application No.: 10/582893 | (our case ref. PN0398). |

The terminal disclaimer is believed to be in compliance with 37 CFR 1.321(c), hence applicants believe that the nonstatutory obviousness-type double patenting rejection has been overcome.

Respectfully submitted,

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